REMARKS

Claims 43-47 currently appear in this application. The Office Action of May 19, 2004, has been carefully studied. These claims define novel and unobvious subject matter under §§102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

In response to the Notice of Non-Compliant Amendment, the claims have been renumbered.

Interview Summary

Applicant's attorney wishes to thank Examiner Mosher for the courtesies extended during the personal interview of July 19, 2004.

The claims discussed during the interview were claims 34-42. The cited prior art discussed was Le et al., U.S. Patent 5,698,195 and Feldmann et al., WO 98/22137.

During the interview, it was proposed to limit the claims to a method for treating hepatitis C, and to reducing the viral levels of a patient, particularly since there were ample data in the specification and the two declarations filed previously to substantiate treating hepatitis C.

As discussed during the interview, the data in the specification and later filed declarations supported treatment of patients suffering from hepatitis C with infliximab and etanercept. The cited references, Le et al. and Feldmann et al., disclosed a great many TNF-mediated pathologies that could be treated by administering anti-TNF antibodies, including alcohol-induced hepatitis. Alcohol-induced hepatitis is not the same as hepatitis C, a viral hepatitis, and therefore one skilled in the art, given the vague allusion to treating TNF-mediated diseases by administering anti-TNF antibodies, would not be motivated to administer infliximab or etanercept to patients suffering from hepatitis C. Moreover, there are warnings in *e.g.*, *The Merck Manual* against administering anti-TNF antibodies or TNF receptor Fc-fusion protein to patients suffering from an infection, which would contraindicate using anti-TNF antibodies for treating hepatitis C.

In discussing the enablement rejection, attention was directed to the specification and two declarations later submitted which provided data on treating hepatitis C with infliximab or etanercept. It should be noted that, although not all patients responded positively, there were sufficient patients who responded to lead one skilled in the art, without

undue experimentation, to treat other patents with hepatitis C with infliximab or etanercept.

While Examiner Mosher did not commit to allowing claims for treating hepatitis C according to the present invention, she did agree to consider such claims.

Rejections under 35 U.S.C. 112

Claims 35, 36 and 38-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

This rejection is respectfully traversed. As was discussed during the July 19, 2004 interview, the specification as filed teaches one skilled in the art how to treat hepatitis C with infliximab or etanercept. The Example given in the specification, beginning at paragraph 0016, describes a patient with active hepatitis which exhibited a marked elevation of serum hepatitis C viral RNA. The patient was administered 25mg of etanercept twice weekly for five weeks. After five weeks of treatment with etanercept, the hepatitis symptoms include viral RNA of 165,000 units (from 985,000 units prior to treatment) and a normalization of liver enzymes, including aspartate transaminase and alanine transaminase.

The specification as filed further states in paragraph 0020 that the compounds that neutralize the activity of secreted TNF can be administered in amounts of from about 5mg to about 125mg once to seven times weekly. The compounds are administered until the patient exhibits no signs of abnormal liver enzymes.

While the specification as filed, and the two declarations filed subsequently, provide clear methods of treating a patient with hepatitis C according to the invention, it should also be noted that Peterson et al., *Annals of the Rheumatic Diseases*: 2003, 62(11), page 1978, states that patients were treated with 25mg etanercept given twice weekly to treat hepatitis C.

Accordingly, it is believed that there is sufficient enablement in the specification and in papers and declarations filed subsequently, to enable one skilled in the art to treat a patient suffering from hepatitis C with infliximab or etanercept.

Art Rejections

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Le et al. Claims 34 and 37 are rejected under 34 U.S.C. 103(a) as being unpatentable over Feldmann et al., WO 98/22137.

This rejection is respectfully traversed. Le et al. and Feldmann et al. teach treating alcohol-induced hepatitis with anti-TNF monoclonal antibodies or TNF antagonists, respectively. As was discussed during the July 19 interview, alcohol-induced hepatitis is not the same as viral hepatitis, which is what is hepatitis C. There could be no reduction of viral load in alcohol-induced hepatitis, as there is no virus involved with alcohol-induced hepatitis.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _____
Anne M. Kornbau
Registration No. 25,884

AMK:ma
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\bn\n\nyum\amin4a\pto\AMD 16Aug04.doc